UNITED STATES DISTRICT COURT
DISTRICT OF NEVADA

UNITED STATES OF AMERICA,

Plaintiff,

v.

BIO HEALTH SOLUTIONS, LLC

and

MARK GARRISON,

Defendants.

Case No.: 3:15-cv-00354-HDM-VPC

~~(Proposed)~~ ORDER GRANTING **CONSENT DECREE OF PERMANENT INJUNCTION**

The United States of America, plaintiff, by its undersigned attorneys, having filed its complaint for injunctive relief against defendants, Bio Health Solutions, LLC ("BHS"), a limited liability company, and Mark Garrison, an individual (collectively, "Defendants"), and Defendants, without admitting or denying the allegations in the Complaint, having appeared and having consented to the entry of this Consent Decree of Permanent Injunction (the "Decree"), without contest and before any testimony has been taken, and the United States of America having consented to this Decree;

IT IS HEREBY ORDERED, ADJUDGED, AND DECREED as follows:

1. This Court has jurisdiction over the subject matter and over all parties to this action under 28 U.S.C. §§ 1331, 1337, and 1345 and 21 U.S.C. § 332 and its inherent equitable authority.

2. The Complaint for Permanent Injunction states a cause of action against Defendants under the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301-399f (the "FDCA").

3. Upon entry of this Decree, Defendants and each and all of their directors, officers, agents, employees, representatives, successors, assigns, attorneys, and any and all persons in active concert or participation with any of them, who have received actual notice of this Decree by personal service or otherwise, are permanently restrained and enjoined, under the provisions of 21 U.S.C. § 332(a) and the equitable authority of this Court, from directly or indirectly doing or causing to be done any of the following acts: introducing or delivering for introduction into interstate commerce,

manufacturing, processing, packaging, labeling, holding, selling, or distributing RenAvast or any other product intended to diagnose, cure, mitigate, treat, or prevent disease, unless and until an approved new animal drug application ("NADA") filed pursuant to 21 U.S.C. § 360b(b) is effective with respect to that product, or that product meets the requirements for the investigational new animal drug exemption pursuant to 21 U.S.C. § 360b(j) and 21 C.F.R. Part 511.

4. Upon entry of this Decree, Defendants and each and all of their directors, officers, agents, employees, representatives, successors, assigns, attorneys, and any and all persons in active concert or participation with any of them, who have received actual notice of this Decree by personal service or otherwise, are permanently restrained and enjoined, under the provisions of 21 U.S.C. § 332(a) and the equitable authority of this Court, from directly or indirectly doing or causing to be done any act that violates 21 U.S.C. § 331(a) by introducing and/or causing to be introduced, and/or delivering or causing to be delivered for introduction, into interstate commerce, any new animal drug that is adulterated within the meaning of 21 U.S.C. § 351(a)(5).

5. Representatives of FDA shall be permitted, without prior notice and as and when FDA deems necessary, to make inspections of Defendants' places of business, collect samples, and, without prior notice, take any other measures necessary to monitor and ensure continuing compliance with the terms of this Decree. During such inspections, FDA representatives shall be permitted access to Defendants' places of business including, but not limited to, all buildings, equipment, in-process or unfinished and finished materials and products, containers, labeling, and other promotional material therein; to take photographs and make video recordings; to take samples – without charge to FDA – of Defendants' finished and unfinished materials and products, containers and packaging material therein, labeling, and other promotional material; and to examine and copy all records relating to the receipt, manufacturing, holding, and distribution of any and all drugs and their components. The inspections shall be permitted upon presentation of a copy of this Decree and appropriate credentials. The inspection authority granted by this Decree is separate from, and in addition to, the authority to conduct inspections under the FDCA, 21 U.S.C. § 374.

6. If, at any time after entry of this Decree, FDA determines, based on the results of an inspection, analyses of samples, a report or data prepared or submitted by Defendants, or any other

information, that Defendants have violated the FDCA or its implementing regulations or have failed to comply with the provisions of this Decree, or that additional corrective actions are necessary to achieve compliance with the FDCA, its implementing regulations, and/or this Decree, FDA may, as and when it deems necessary, notify Defendants in writing of the noncompliance and order Defendants to take appropriate corrective action, including, but not limited to, ordering Defendants to immediately take one or more of the following actions:

A. Cease all manufacturing, holding, and/or distribution of any and all drug(s);

B. Recall specified drugs manufactured, held, and/or distributed by Defendants. Defendants shall, under FDA supervision and pursuant to a plan approved in writing by FDA, destroy all drugs that are in Defendants' possession, custody, or control, for which a recall was initiated. Defendants shall bear the costs of such recall(s), including the costs of destruction and the costs of FDA's supervision at the rates specified in Paragraph 9 of this Decree. Defendants shall be responsible for ensuring that the destruction is carried out in a manner that complies with all applicable federal and state environmental laws; and/or

C. Take any other corrective action(s) as FDA, in its discretion, deems necessary to protect the public health or bring Defendants into compliance with the FDCA, its implementing regulations, or this Decree.

7. The following process and procedures shall apply when FDA issues an order under Paragraph 6 of this Decree, except as provided in subparagraph (D) below:

A. Unless a different time frame is specified by FDA in its order, within ten (10) business days after receiving such order, Defendants shall notify FDA in writing either that:

(1) Defendants are undertaking or have undertaken corrective action, in which event Defendants shall also describe the specific action taken or proposed to be taken and the proposed schedule for completing the action; or

(2) Defendants do not agree with FDA's order. If Defendants notify FDA that they do not agree with FDA's order, Defendants shall explain in writing the basis for their disagreement. In so doing, Defendants also may propose specific alternative action and specific time frames for achieving FDA's objectives.

B. If Defendants notify FDA that they do not agree with FDA's order, FDA will review Defendants' notification and thereafter, in writing, affirm, modify, or withdraw its order, as FDA deems appropriate. If FDA affirms or modifies its order, it will explain the basis for its decision in writing. The written notice of affirmation or modification shall constitute final agency action.

C. If FDA affirms or modifies its order, Defendants shall, upon receipt of FDA's order, immediately implement the order (as modified, if applicable), and if they so choose, bring the matter before this Court. While seeking Court review, Defendants shall continue to diligently implement FDA's order, unless the Court sets aside, stays, reverses, vacates, or modifies FDA's order. Any review of FDA's decision under this paragraph shall be made in accordance with the terms set forth in Paragraph 14 of this Decree.

D. The process and procedures set forth above in subparagraphs A-C above shall not apply to any order issued under Paragraph 6 of this Decree if such order states that, in FDA's judgment, the matter raises significant public health concerns. In such case, Defendants shall immediately and fully comply with the terms of that order. Should Defendants seek to challenge any such order, they may petition this Court for relief while they implement FDA's order. Any review of FDA's decision under this paragraph shall be made in accordance with the terms set forth in Paragraph 14 of this Decree.

8. Any cessation of operations or other action described in Paragraph 6 of this Decree shall continue until Defendants receive written notification from FDA that Defendants appear to be in compliance with the FDCA, its implementing regulations, and this Decree, and that Defendants may, therefore, resume operations. Upon Defendants' written request to resume operations, FDA will promptly determine whether it needs to inspect any of Defendants' facilities to determine Defendants' compliance with the law and this Decree. If FDA determines that an inspection is necessary, it will conduct the inspection within sixty (60) calendar days after such determination, and, within thirty (30) calendar days following the close of the inspection, determine whether Defendants appear to be in compliance with the law and this Decree and, if so, FDA will issue to Defendants a written notification permitting resumption of operations. If FDA determines that no

inspection is necessary, FDA will decide within forty-five (45) calendar days after receipt of the request whether Defendants appear to be in compliance and, if so, issue to Defendants a written notification permitting resumption of operations. In no circumstances shall FDA's silence be construed as a substitute for written notification. All costs of recall(s) and corrective actions ordered by FDA pursuant to Paragraph 6 of this Decree shall be borne by Defendants. The costs of FDA inspections, sampling, testing, travel time, and subsistence expenses to implement the remedies set forth in Paragraph 6 of this Decree shall be borne by Defendants at the rates specified in Paragraph 9 of this Decree. This provision shall be separate and apart from, and in addition to, all other remedies available to FDA.

9. Defendant BHS shall pay all costs of FDA's supervision, inspections, investigations, analyses, examinations, and reviews that FDA deems necessary to evaluate Defendants' compliance with this Decree, at the standard rates prevailing at the time the costs are incurred. As of the date that this Decree is signed by the parties, these rates are: $89.35 per hour and fraction thereof per representative for inspection work; $107.90 per hour or fraction thereof per representative for analytical or review work; $0.575 per mile for travel by automobile; government rate or the equivalent for travel by air or other means; and the published government per diem rate or the equivalent for the areas in which the inspections are performed per representative and per day for subsistence expenses, where necessary. In the event that the standard rates applicable to FDA supervision of court-ordered compliance are modified, these rates shall be increased or decreased without further order of the Court.

10. Within ten (10) days after the entry of this Decree, Defendants shall provide a copy of this Decree, by personal service or registered mail, to each and all of their directors, officers, agents, employees, representatives, successors, assigns, attorneys, and any and all persons in active concert or participation with any of them (including "doing business as" entities) (collectively referred to as "Associated Persons"). Within thirty (30) days after entry of this Decree, Defendants shall provide to FDA an affidavit of compliance, signed by a person with personal knowledge of the facts, stating the fact and manner of compliance with the provisions of this Paragraph and identifying the names, addresses, and positions of all persons who have received a copy of this Decree and the manner of

notification. In the event that Defendants becomes associated with any additional Associated Person(s) at any time after entry of this Decree, Defendants immediately shall provide a copy of this Decree, by personal service or certified mail (restricted delivery, return receipt requested), to such Associated Person(s). Within thirty (30) days after the commencement of each such association, Defendants shall provide to FDA an affidavit stating the fact and manner of their compliance with this Paragraph, identifying the names, addresses, and positions of all Associated Persons who received a copy of this Decree pursuant to this Paragraph, and attaching a copy of the executed certified mail return receipts. Within ten (10) days after receiving a request from FDA for any information or documentation that FDA deems necessary to evaluate Defendants' compliance with this Paragraph, Defendants shall provide such information or documentation to FDA.

11. Defendants shall notify FDA in writing at least fifteen (15) days before any change in ownership, character, or name of their businesses, including incorporation, reorganization, bankruptcy, assignment, or sale resulting in the emergence of a successor business or corporation, the creation or dissolution of subsidiaries, or any other change in the corporate structure or identity of the Defendants' business, or in the sale or assignment of any business assets, such as buildings, equipment, or inventory, that may affect obligations arising out of this Decree. Defendants shall provide a copy of this Decree to any potential successor or assign at least fifteen (15) days before any sale or assignment. Defendants shall furnish FDA with an affidavit of compliance with this Paragraph no later than ten (10) days prior to such assignment or change in ownership.

12. If Defendants fail to comply with any of the provisions of this Decree, including any time frame imposed by this Decree, then Defendant BHS shall pay to the United States of America: five thousand dollars ($5,000) in liquidated damages for each violation of the FDCA, its implementing regulations, and/or this Decree, and an additional sum of five thousand dollars ($5,000) in liquidated damages for each day such violation continues; and further additional sum equal to three times the retail value of any drugs that have been distributed in violation of this Decree. Defendants understand and agree that the liquidated damages specified in this Paragraph are not punitive in nature and their imposition does not in any way limit the ability of the United States

to seek, or the power of the Court to impose, additional criminal or civil penalties or remedies based on conduct that may also be the basis for payment of liquidated damages pursuant to this Paragraph.

13. Should the United States of America bring, and prevail in, a contempt action to enforce the terms of this Decree, Defendants shall, in addition to other remedies, pay all attorneys' fees and costs, travel expenses incurred by attorneys and witnesses, expert witness fees, investigational and analytical expenses, and court costs incurred by Plaintiff in bringing such an action.

14. Defendants shall abide by FDA's decisions, and FDA's decisions shall be final. All decisions conferred upon FDA in this Decree shall be vested in FDA's discretion and, if contested, shall be reviewed by this Court under the arbitrary and capricious standard set forth in 5 U.S.C. § 706(2)(A). Review by the Court of any FDA decision rendered pursuant to this Decree shall be based exclusively on the written record before FDA at the time of the decision. No discovery shall be taken by either party.

15. A party may at any time petition the other party in writing to extend any deadline provided for herein, and such extension may be granted by the other party in its sole discretion without seeking leave of Court.

16. All notifications, certifications, reports, correspondence, and other communications to FDA required by the terms of this Decree shall be marked "Consent Decree Correspondence" and shall be addressed to the Director, FDA San Francisco District Office, 1431 Harbor Bay Parkway, Alameda, CA 94502.

17. This Court retains jurisdiction of this action and the parties thereto for the purpose of enforcing and modifying this Decree and for the purpose of granting such additional relief as may be necessary or appropriate.

18. If Defendants petition the Court for relief from this Decree and, at the time of the petition, in FDA's judgment, Defendants have maintained a state of continuous compliance with this Decree, the Act, and all applicable regulations for the preceding sixty (60) months, Plaintiff will not oppose such petition.

IT IS SO ORDERED, this 10th day of July, 2015.

Howard D McKibben

UNITED STATES DISTRICT JUDGE

Page 8 of Consent Decree of Permanent Injunction
USA vs. Bio Health Solutions, LLC and Mark Garrison 3:15-cv-354-HDM-VPC

WE HEREBY AGREE TO THE ENTRY OF THE ABOVE CONSENT DECREE

FOR THE DEFENDANTS:

Dated: 06/19/2015

MARK GARRISON
Individually and on behalf of
Bio Health Solutions, LLC

Dated: 7/1/2015

TODD A. HARRISON
VENABLE LLP
575 7th Street, N.W.
Washington, DC 20004
(202) 344-4724 (office)
(202) 344-8300 (facsimile)
taharrison@Venable.com

Dated: 6/29/2015

RALPH S. TYLER
VENABLE LLP
750 East Pratt Street, Suite 900
Baltimore, MD 21202
(410) 244-7436 (office)
(410) 244-7742 (facsimile)
rtyler@Venable.com

Attorneys for Defendants
Bio Health Solutions, LLC and
Mark Garrison

FOR PLAINTIFF:

DANIEL G. BOGDEN
United States Attorney
GREG ADDINGTON
Assistant United States Attorney

BENJAMIN C. MIZER
Principal Deputy Assistant Attorney General
Civil Division
United States Department of Justice
JONATHAN F. OLIN
Deputy Assistant Attorney General
MICHAEL S. BLUME
Director, Consumer Protection Branch

Dated: 7/9/2015

DAVID A. FRANK
Trial Attorney
United States Department of Justice
Consumer Protection Branch
P.O. Box 386
Washington, DC 20044
(202) 307-0061
David.Frank@usdoj.gov

OF COUNSEL:

WILLIAM B. SCHULTZ
General Counsel
ELIZABETH H. DICKINSON
Chief Counsel
Food and Drug Division
ANNAMARIE KEMPIC
Deputy Chief Counsel for Litigation
STEVEN J. TAVE
Associate Chief Counsel
United States Department
of Health and Human Services
Office of General Counsel
U.S. Food and Drug Administration
Building 32, Room 4386
10903 New Hampshire Avenue
Silver Spring, MD 20993